



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,736	03/23/2004	Jerome David	SPINE 3 . 0-423	2555
530	7590	02/16/2006	EXAMINER	
LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090			SHAFFER, RICHARD R	
			ART UNIT	PAPER NUMBER
			3733	

DATE MAILED: 02/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

e

Office Action Summary	Application No. 10/806,736	Applicant(s) DAVID, JEROME	
	Examiner Richard R. Shaffer	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>9/13/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The following title is suggested: Modular Polyaxial Bone Screw and Plate.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 8 recites the limitation "said fingers" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 25, 26, and 30-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Shluzas, et al (US Patent Publication 2002/0143328). Shluzas, et al disclose a bone plate system (**Figure 5**) comprising: a curved (see **Figure 3**) bone plate (**212**) having a first aperture (**250**), second aperture (**252**), and a third aperture (**254**) extending along a longitudinal axis and having an upper and lower surface; a sliding

Art Unit: 3733

element having a top (242) and bottom (270) portion, an aperture extending along a central axis, the top portion having a compression member (lower portion of top 242), the bottom portion having a locking member (upper portion of 270), both the top and bottom portions having inwardly tapered walls (the top is internal, the bottom is external at the base where it interfaces with 240), both portion have a radially outward extending shoulder (286 and 294), and both portions interact with an interior wall of the bone plate aperture (250); a bone fastener (216) having a longitudinal axis, stem which is orientated within the sliding element aperture; a stopping element (240); a threaded locking element (228) having a bore for receiving the stem of the bone screw and includes a concave base (206) and a cap (more easily seen in **Figure 3**). In Column 5, Paragraph 57, it is further disclosed that the stopping element could have a convex surface with the bottom element having a concave surface to interact. In regard to claims 30-33, **Figure 3** clearly demonstrates applicant's method steps.

Claims 1-13, 16-18, and 25-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Lin (US Patent 5,613,968). Lin discloses a system (**Figure 8**) comprising: a bone screw (300) having a longitudinal axis, having a stem (330) and a bone engaging portion (31); a bone plate (100) having an aperture (130) extending along the longitudinal axis of the bone screw; a sliding element with top (200) and bottom (323) portion, the top portion having a compression member (230) with a plurality of inwardly tapered fingers (250, **Figure 3c**) which also have a ridge (bottom of 200, see **Figure 3c**), the bottom portion having a locking member (edges of 323) to engage the compression member, an aperture passing through wherein the diameter of the screw

Art Unit: 3733

stem is less than the cross section of the aperture, and both the top and bottom portions having a radially extending outer wall (**210** and **323**); a stopping element (**322**); a threaded locking element (**400**) having a concave base (**430**) and cap (**410**).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 5-7, and 9-14, 16-19, and 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shluzas, et al. Shluzas, et al disclose all of the claimed limitations except for the stopping element being separable and adjustable by threading. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the stopping element (**240**) separate from the shaft of the bone screw, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlichman*, 168 USPQ 177, 179.

Claims 15 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shluzas, et al. It would have been further obvious to one having ordinary skill in the art at the time the invention was made to construct the removable stopping element (**240**) with internal threads, since it has been held that the provision of adjustability, where needed, involves only routine skill in the art. *In re Stevens*, 101 USPQ 284 (CCPA 1954).

Art Unit: 3733

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard R. Shaffer whose telephone number is 571-272-8683. The examiner can normally be reached on Monday-Friday during (7am-5pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Richard Shaffer

Richard Shaffer
February 9th, 2006


EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER